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SAFETY IN NATIONAL CARE - REAL WORLD DATA FROM THE GERMAN PSORIASIS-REGISTRY "PSOBEST"

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OBJECTIVES: The registry "PsoBest" observes systemic therapy of moderate and severe psoriasis/psoriasis-arthritis in Germany since 2008. The registry is supported by the German society for dermatologists, the association of dermatologists, pharmaceutical manufactures, dermatologists and patients. It is located at CVderm and documents safety, effectiveness and patient benefit in routine health care. One purpose of PsoBest is to monitor the safety of systemic antipsoriatics. **METHODS:** Patients receiving first time a conventional systemic or biologic treatment are observed for 5 years, regardless of therapy switches. Standardised questionnaires for physicians and patients are compiled. Adverse and serious adverse events (AE/SAE) are coded in MedDRA and analyzed twice a year. **RESULTS:** Pharmacovigilance after 42 months on 1984 patients with 800 expositions to biologics (1196 patient years) and 1430 to systemics (1548 patient years) resulted in 187 SAE codings in 121 patients (6.1%). A total of 105 SAE were observed under biologic and 95 under conventional systemic treatment (8.9 and 4.5%, respectively). Of these, 20 SAE in 14 patients were observed in combined treatment. By system-organ-classes, general disorders and administration site conditions were observed for 2.3% of biologic (1.51 events/100 patient years) and 1.3% systemic patients (1.32 events/100 patient years). The rates for cardiac disorders were 0.92 (1.4% of patients) and 0.84 (0.9% of systemic patients), respectively. For infections and infestations the rates were 0.84 (1.3%) and 0.52(0.8%) and for neoplasms benign, malignant and unspecified (incl. cysts and polyps) 0.67 (1.0%) and 0.71 (0.8%). **CONCLUSIONS:** PsoBest provides urgently needed long-term safety data in the systemic treatment of psoriasis and psoriatic-arthritis from routine care in Germany. To date, no safety concern emerged from the registry. To raise the power for signal detection, verification, analysis and assessment, PsoBest is proactively contributing to the European surveillance of effectiveness and safety of systemic psoriasis therapy (ENCEPP-network psonet).

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AFLIBERCEPT IN NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION: AN ANALYSIS OF THE PAYER DECISION LANDSCAPE

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OBJECTIVES: To investigate and analyse decisions of Health Technology Assessment or national drug reimbursement agencies for aflibercept in neovascular (wet) aged-related macular degeneration, including decision outcomes, the rationale for these, the data package and any payer critique of the manufacturer approach. **METHODS:** A search of decision-making agency websites in key European markets, Canada and Australia was conducted to identify relevant decisions. Data were extracted and used to conduct a qualitative analysis of decisions. **RESULTS:** Five decisions were identified; from NICE (England & Wales), SMC (Scotland), HAS (France), G-BA (Germany) and PBAC (Australia). In all instances, the clinical and economic arguments, where applicable, were based on demonstration of non-inferiority of aflibercept to an existing therapy, ranibizumab. These arguments were supported by two key trials of aflibercept vs. ranibizumab: VIEW 1 and 2, and also indirect comparisons and network meta-analyses. In all decisions, aflibercept was either recommended for the full licensed indication or recommended with restrictions. All agencies commented that the key trials were well conducted and unbiased; however, they also state that the dosing schedule for ranibizumab did not reflect the license or clinical practice in respective markets, and it was unclear if there would be any difference in the frequency of injections between therapies in the clinical setting. Furthermore, for the economic models for NICE, SMC and PBAC, the respective agencies thought the frequency of injections and number of clinician visits for ranibizumab were overestimated. All agencies concluded that aflibercept demonstrated no additional clinical benefit over ranibizumab. For example, HAS in France granted an ASMR level V: no improvement in clinical benefit, while NICE recommended that aflibercept be used in accordance with their recommendations for ranibizumab. **CONCLUSIONS:** While aflibercept is an effective alternative therapy to ranibizumab, payers have concluded that it offers no demonstrable added clinical benefit compared with ranibizumab.

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HEALTH RELATED QUALITY OF LIFE-OUTCOME IN NATIONAL CARE - REAL WORLD DATA FROM THE GERMAN PSORIASIS-REGISTRY "PSOBEST"

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OBJECTIVES: The registry "PsoBest" observes systemic therapy of moderate and severe psoriasis/psoriasis-arthritis in Germany since 2008. The registry is supported by the German society for dermatologists, the association of dermatologists, pharmaceutical manufactures, dermatologists and patients. It is located at CVderm and records efficacy, safety, and patient benefit in routine health care. One purpose of PsoBest is to monitor health related quality of life (HrQoL) and severity of psoriasis in the process of care. **METHODS:** Patients receiving first time a conventional systemic or biologic therapeutic are observed for 5 years, independent of further treatment. Standardised questionnaires for physicians and patients are compiled. Main outcomes are severity (PASI), affected body surface area (BSA) and HrQoL (DLQI and EQ-5D). **RESULTS:** A total of 1,984 patients were enrolled up to July 2012 (60% male, mean age of 47 years); mean duration of illness was 19±14 years. Patients on biologics (n=686) tended to be male (63 v. 58%), older (48.1 v. 46.7 years) as patients on conventional systemics (n=1,298) and had a longer history of psoriasis (21.9 v. 16.8 years). The biologic cohort showed more nail involvement (64 v. 52%), signs of arthritis (47 v. 17%), higher severity (PASI: 15.6 v. 14.6; BSA: 22. v. 21.5) and lower HrQoL (DLQI: 11.7 v. 11.0; EQ-5D VAS: 50.6 v. 55.7). For the biologics cohort, mean PASI improved to 4.5 between 12 and 24 months (reduction of 70% from baseline). Moreover, HrQoL (DLQI) improved by 65% from inclusion. The conventional systemics cohort showed comparable reduction in PASI=3.1 (77%) but less improvement in DLQI= 3.1 (49%). **CONCLUSIONS:** PsoBest provides long-term real-world data on psoriasis care in Germany. The results show the high burden of psoriasis patients entering the registry and also the high quality of care and patient benefit after initiation of systemic treatment.

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RECRUTING PHYSICIANS FOR HEALTH OUTCOME AND POST-APPROVAL STUDIES: BENEFITS OF A MANAGED PHYSICIAN PANEL

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OBJECTIVES: Access to multi-country physician panels is an alternative option to recruit medical sites for health outcome or post-approval studies, compared to the conventional approach of individually recruiting clinical expert sites. The objective of our study was to assess the potential of physician panels for site recruitment. **METHODS:** In 2012, a representative survey among members of a managed physician panel (All Global's managed panel of ophtalmologists in US, UK, GER, FR, IT and SP) was conducted. The survey assessed the willingness of the physicians to participate in post-approval studies. Information about former participation in those studies and commitment to special requests for post-approval studies (e.g. ethical committee involvement, advent reporting to sponsor, security of patient's informed consent) were also collected. **RESULTS:** A total of 200 opthalmologists participated in the survey. Since no special incentive was offered for participation the response rate of more than 25% was satisfactory. 79 (39,5%) of the physicians formerly participated in clinical trials and 95 (47,5%) in post-approval studies. 54,5% of the ophtalmologists were willing to participate in future studies. More than 80% of this group was ready to ask their hospital or other legal authorities for permission to participate in studies of this kind, to report serious adverse events to the sponsor of the study and to ask patients for written informed consent. **CONCLUSIONS:** Managed physician panels are a valuable alternative option to recruit medical sites for post-approval or health outcome studies. Every second ophtalmologist from panels is experienced in this kind of studies and most of them are willing fullfil all necessary legal and quality requirements. In addition to timing and cost factors, an adavantage of physician panels is the better representation of daily medical routine-practice, adding to the epidemiological validity of respective projects.

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LYMPHEDEMA – THE LONG WAY TO DIAGNOSIS AND THERAPY

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OBJECTIVES: Clinical experience indicates that edema often remain undiagnosed. The aim of this study was to examine how much time passes between important events in the 'patient journey' and what predicts late consultation and diagnosis. **METHODS:** Sixty-five patients with secondary arm lymphedema and 161 patients with primary or secondary leg lymphedema were interviewed. The following latency times were computed: time between 1) first symptoms and first visit to physician; 2) visit to physician and diagnosis; 3) diagnosis and lymph drainage therapy; and 4) diagnosis and compression therapy. Associations of latency times with patient and clinical characteristics were analysed using t tests and multivariate linear regression. **RESULTS:** All arm edema patients had consulted a physician in the year after first symptoms at the latest, and everyone except two received the diagnosis in the following year at the latest. For secondary leg edema, the average latency until physician consultation was also short with 0.5 ± 1.8 years, and latency until diagnosis was 1.7 ± 3.8 years. In contrast, latencies in primary leg edema were significantly longer: The average time between first symptoms and physician consultation was 5.2 ± 11.0 years, and edema diagnosis was made after further 6.7 ± 11.4 years. On average, it took 13.5 years from first symptoms to lymph drainage therapy in these patients and 13.7 years until compression therapy. Predictors of late consultation and late diagnosis in primary leg edema were age<40, positive family anamnesis, and female gender. **CONCLUSIONS:** Primary leg lymphedema are diagnosed late in many cases, especially in younger women.

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ADHERENCE BY SPANISH RETINOLOGISTS TO THE GUIDANCE FOR THE MANAGEMENT OF PATIENTS WITH WET AGE-RELATED MACULAR DEGENERATION

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OBJECTIVES: To assess the adherence by Spanish retinologists to the recommendations for the management of age-related macular degeneration (AMD) published by the Spanish Society of Retina and Vitreous (SERV). **METHODS:** Non-interventional, retrospective and multicenter study, involving 59 researchers from different Spanish Ophthalmology Services that collected medical records from 346 patients aged ≥50 years and diagnosed with exudative AMD. **RESULTS:** Adherence to SERV-guidelines by Spanish retinologists was high concerning diagnostic (96.8%) and control items (98.6%) of AMD patients, slightly lower for therapeutic issues (84.4%), and much lower on patient follow-up and retreatment criteria (46.9%). When focusing on diagnostic, first symptoms indicative of wet AMD were sharp and progressive loss of visual acuity (64.7%), followed by metamorphopsia (distorted vision) (33.8%) and central scotoma (23.1%). Main diagnostic confirmatory tests were visual acuity (97.1%), OCT (93.4%), biomicroscopy (92.2%) and fluorescein angiography (71.1%). For therapeutic issues, first choice treatment was based on anti-VEGF-drugs (99.1%), mainly ranibizumab (96.8%) as a loading dose of three injections (88.1%). Main patient follow-up tests were: visual acuity tests (98.0%), optical coherence tomography (96.0%), biomicroscopy (91.9%). Most common control schemes during the first year of treatment were every-two-months (35.8%) or monthly (30.4%) visits;